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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,697	08/14/2002	Ajay Kumar Luthra	16230-8677	8586

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
02/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDOCKET@THOMPSONCOBURN.COM

Office Action Summary	Application No.	Applicant(s)	
	09/980,697	LUTHRA ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/07 has been entered.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 44-66 have been renumbered 43-65.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 39-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. Applicant has amended the claims to include the limitation that "... a tertiary amino group remains in a bound biguanide residue.", however these tertiary amino groups are not disclosed anywhere in the specification. Applicant indicates that through the chemistry demonstrated in the specification, the tertiary amine groups *should* be present and still bound to the biguanide residue, yet provides not evidence of their existence. The schemes present in Specification are silent to tertiary amine group being bound to the biguanide residue. This lack of disclosure would prevent a person of ordinary skill from making of using the invention since the formula of the instant claims lacks tertiary amine groups, and the Specification is silent to either existence.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 39-66 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. First the claims recite a biguanide formula –NH-C(NH)-NH-C(NH)-NH- without disclosing what is attached to either end of the compound. It is unclear how this compound is attached to anything and what pendent groups can be attached. Secondly the claims recite that tertiary amino groups are bound in a biguanide residue. This is unclear since the compound formula does not appear to possess any tertiary amino groups. If they are not present how can they be bound within a residue?

8. For the purposes of Examination until evidence can be present to the existence of tertiary amine groups, and until an explanation to how these groups fit within the Schemes proposed by Applicant the limitation will be ignored.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 39-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures Olstein (USPN 5,142,010 hereafter '010) and Solomon et al (USPN 5,451,424 hereafter '424). The claims are drawn to a polymeric biguanide and a method of making the same. The biocidal polymer is bound by some but not al of the secondary amine groups, where a tertiary amine group remains in a bound biguanide residue.

4. The '010 patent teaches a polymeric biguanide formulation where one of the nitrogen atoms is bond by an amine linkage (col. 2, lin. 15-65). The polymer formed is infection resistant

and is useful in bulk polymers and copolymers (col. 3, lin. 49-65). The polymeric material is incorporated into various forms useful in or on the human body and as a coating, or an implantable medical device (col. 4, lin. 54-65; col. 13, lin. 21-36). The reaction sites binding to the polymer include isocyanate (col. 2, lin. 56-60). The polymers are subsequently blended with other polymers such as acrylic acid derivatives and methacrylate derivatives (col. 9, lin. 50-65). The formation of the polymer requires a polymerization process (col. 10, lin. 51-68). The process includes the incorporation of a carbodiimide (Example III). The polymers are combined with polymers useful for ocular lenses such as silicones (col. 12, lin.20-25). The reference is silent to the specific biguanide compound useful in making the biocidal polymers, however various biguanide compounds are well known to those of ordinary skill in the art. These compounds can be found in the '424 patent.

5. The ‘424 patent discloses a biguanide polymer comprising chlorhexidine (abstract). The biguanide is bound to polyurethane and used for medical tubing (example 1). Polyurethane is one of the many polymers used in grafting the biguanides of the ‘010 patent, therefore a skilled artisan would be motivated to include the biguanides of the ‘424 into the preparation of the ‘010.

6. The combination is silent to the tertiary amine groups being bound to a biguanide residue, however the combination of provides a biocidal polymer using the same compounds as the instant claims. Tertiary amino groups would be expected in charged biguanide compounds such as chlorhexidine or polyhexanide. Chlorhexidine is the biguanide used in the ‘424 patent. It would have been obvious to combine the specific biguanide compound of the '424 into the polymers of the '010 since each reference teaches similar polymeric structures and uses. The tertiary amine groups would be an inherent by product of the polymerization process. The ''010

patent provides a method of making biocidal polymeric compounds comprising the combination of biguanide compounds with polymeric structures where the bonds occur at isocyanate reactive sites along the polymer chain, and carbodiimide coupling agents are used. According to the specification a partial free base must be formed when using chlorhexidine or polyhexanide, thus this step is also obviously be taken by one of ordinary skill in the art follow the teachings and suggestions of the prior art combination.

7. With these things in mind it would have been obvious to incorporate the biguanides of the '424 patent into the preparation of the '010 in order to fight a wide range of bacterial infections. It would have been obvious to one of ordinary skill in the art to combine these teachings and suggestions since both reference provide similar polymeric structures, while the '424 patent provides specific polymers and medical device structures. One of ordinary skill in the art would have been motivated to combine the teachings and references with an expected result of an infection resistant polymer useful in medical device applications.

Response to Arguments

8. Applicant's arguments filed 11/19/07 have been fully considered but they are not persuasive. Applicant argues that:

a. The combination of the '010 and '424 patents is insufficient since it does not disclose the tertiary amino groups of the instant claims.

9. Regarding arguments a., it is the position of the Examiner, as discussed above that these tertiary amino groups are an inherent feature resulting form the polymerization reaction comprising a charged biguanide such as chlorhexidine or polyhexanide. Such a reaction is

provided in the combination of the ‘010 and ‘424 patents. The '424 patent provides the specific biguanide while the ‘010 patent provides a polymerization process comprising a carbodiimide coupling agent. The resultant polymer would be resistant to infections and useful in biomedical devices such as intraocular lenses and medical tubing. For these reasons the claims remain rejected.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Buckley (GB 1531717) discloses a biocidal polymer comprising a biguanide compound.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

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/Michael G. Hartley/

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